UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JENNIFER DAVIS and BRYAN DAVIS, Plaintiffs, v. BAYER CORPORATION, BAYER U.S. LLC, BAYER HEALTHCARE LLC, BAYER ESSURE INC., BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER AG, BAYER PHARMA AG, CONCEPTUS SAS, and BAYER S.A., Defendants.	:	Case No.

NOTICE OF REMOVAL

Defendants Bayer Corporation, Bayer U.S. LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc. (together, "Bayer"), by and through their undersigned counsel, hereby provide notice pursuant to 28 U.S.C. §§ 1332, 1441, and 1446 of the removal of the above-captioned case from the Court of Common Pleas in Philadelphia County to the United States District Court for the Eastern District of Pennsylvania. The grounds for removal are as follows:

BACKGROUND

1. On October 1, 2018, Plaintiffs Jennifer Davis and Bryan Davis filed a complaint for damages in Pennsylvania state court. The complaint alleges that Plaintiff "suffered from severe and permanent injuries" as a result of her experience using Essure, an FDA pre-market

approved Class III medical device that serves as a form of permanent birth control. Compl. ¶ 118 (Ex. A, hereto).

2. Essure was approved by FDA through the rigorous premarket approval ("PMA") process in 2002. Ex. B (Premarket Approval Order). Since then, FDA has granted numerous supplemental approvals, including as recently as April 2018, *see* Ex. C (FDA website noting PMA Supplements), repeatedly reviewing and approving Essure's design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling. *See generally Norman v. Bayer Corp.*, No. 3:16-cv-253(JAM), 2016 WL 4007547 (D. Conn. July 26, 2016) (recounting Essure regulatory history and dismissing all claims with prejudice as preempted by federal law); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 809-11 (E.D. Pa. 2016) (recounting Essure regulatory history and dismissing 10 of 12 claims). After a public hearing in September 2015 and months of investigation, FDA reaffirmed that "FDA continues to believe that the benefits of the device outweigh its risks." Ex. D (FDA Activities: Essure).

ARGUMENT

3. As set forth more fully below, this case is properly removed because this Court has diversity jurisdiction under 28 U.S.C. § 1332. There is complete diversity among the parties: Plaintiff is a citizen of Virginia, and no defendant is a citizen of that state. Moreover, the amount in controversy exceeds $75,000.

I. THE PROCEDURAL REQUIREMENTS OF REMOVAL ARE MET.

4. Pursuant to 28 U.S.C. § 1446(a), true and correct copies of all process, pleadings, orders and other documents filed in the state court action are attached as Exhibit A.

5. Plaintiffs have not yet served their complaint on Defendants.[1] Section 1446(b)(1) requires a notice of removal to be filed within 30 days of the service of a complaint upon the defendants. *See Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354 (1999) (30-day time limit for removal runs from date of formal service of the initial complaint). Because the complaint has not yet been served, this Notice of Removal is timely filed.

6. The United States District Court for the Eastern District of Pennsylvania presides in the locality in which the state court action is now pending. It is therefore a proper forum for removal. *See* 28 U.S.C. §§ 118(a), 1441(a).

7. A copy of this Notice of Removal is being served on Plaintiffs, and a copy is being filed with the state court. *See id.* § 1446(d).

8. If any questions arise about this removal, Bayer respectfully requests the opportunity to present briefing and oral argument in support of removal.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441.

9. A defendant may remove an action from state court to federal court if the action could have been brought originally in federal court. *See* 28 U.S.C. § 1441. Here, federal jurisdiction exists based upon diversity of citizenship pursuant to 28 U.S.C. § 1332, because this is a civil action between citizens of different states, and it is facially apparent that the amount in controversy with respect to Plaintiff's claim exceeds $75,000, exclusive of interest and costs. *See id.* § 1332(a); *Auto-Owners Ins. Co. v. Stevens & Ricci Inc.*, 835 F.3d 388, 394-95 (3d Cir. 2016).

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[1] At the time that this notice of removal was filed, Plaintiffs have not yet served the defendants in this matter, and they reserve all rights, including objections to service and personal jurisdiction. *See City of Clarksdale v. BellSouth Telecomms., Inc.*, 428 F.3d 206, 214 n.15 (5th Cir. 2005) ("A defendant's removal to federal court does not waive its right to object to service of process." (citing *Morris & Co. v. Skandinavia Ins. Co.*, 279 U.S. 405, 409 (1929)).

A. The Amount-In-Controversy Exceeds $75,000.

10. Although Plaintiff does not specifically allege the amount of damages in her complaint, beyond noting that it involves claims worth more than $50,000, it is facially apparent that the damages sought, including any punitive damages, exceed $75,000. *See* 28 U.S.C. § 1446(c)(2); *see, e.g.*, *Huber v. Taylor*, 532 F.3d 237, 244 (3d Cir. 2008) (recognizing that claims for punitive damages are included in determining the amount in controversy). Plaintiff alleges that she sustained "severe and permanent injuries." Compl. ¶ 118. Further, she states that she "has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses" and that she "has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity." *Id.* ¶¶ 182-83.

11. Courts have found the amount in controversy satisfied in similar cases, in which plaintiffs have asserted similar injuries, alleged similar degrees of pain, and requested punitive damages. *See, e.g.*, *Dyson v. Bayer Corp.*, 2018 WL 534375, at *5 (E.D. Mo. Jan. 24, 2018) (finding diversity jurisdiction once non-diverse plaintiffs dismissed for lack of personal jurisdiction); *Hocker v. Klurfield*, 2015 WL 8007463, at *2 (E.D. Pa. Dec. 7, 2015) (collecting cases).

12. Moreover—although Bayer denies that any relief is warranted—Pennsylvania juries routinely award compensatory damages in excess of $75,000 in product liability cases where liability is found, further supporting the conclusion that the jurisdictional minimum requirement is satisfied. *See, e.g.*, *Yount v. Janssen Pharm., Inc.*, 2016 Jury Verdicts LEXIS 4652 (July 1, 2016) ($70 million verdict in pharmaceutical case); *Carlino v. Ehticon, Inc.*, 2016 Jury Verdicts LEXIS 841 (Feb. 10, 2016) ($13.5 million verdict in medical device case). Thus,

given the nature of Plaintiff's alleged injuries, the scope of damages sought, and the lack of any express limitation on the amount of damages sought, Plaintiff's claims plainly satisfy the amount-in-controversy requirement.

B. Complete Diversity Of Citizenship Exists.

13. There is complete diversity of citizenship between the parties.

14. Plaintiff alleges that Defendant Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Compl. ¶ 3. In fact, since January 1, 2017, Bayer Corporation's principal place of business has been in New Jersey. Accordingly, it is a citizen of Indiana and New Jersey for diversity purposes. *See* 28 U.S.C. § 1332(c).

15. Plaintiff alleges that Defendant Bayer U.S. LLC is a Pennsylvania corporation with its principal place of business in Pittsburgh, Pennsylvania. Compl. ¶ 4. In fact, Bayer US LLC is a limited liability company, and its citizenship is determined by the citizenship of its members. *Brand Mktg. Grp. LLC v. Intertek Testing Servs., N.A., Inc.*, 801 F.3d 347, 353 (3d Cir. 2015). Its sole member is Bayer Corporation, and thus, Bayer U.S. LLC is a citizen of Indiana and New Jersey for diversity purposes. *See* 28 U.S.C. § 1332(c).

16. Defendant Bayer HealthCare LLC is a citizen of Delaware, Pennsylvania, New Jersey, Germany, and the Netherlands. Compl. ¶ 5. Like Bayer U.S. LLC, Bayer HealthCare LLC's citizenship is determined by the citizenship of its nine members. *Brand Mktg.*, 801 F.3d at 353. Those members are:

- NippoNex Inc., a Delaware corporation with its principal place of business in New Jersey;
- Bayer West Coast Corporation, a Delaware corporation with its principal place of business in New Jersey;

- Bayer Essure Inc., a Delaware corporation with its principal place of business in New Jersey;
- Bayer Medical Care Inc., a Delaware corporation with its principal place of business in Pennsylvania;
- Bayer Consumer Care Holdings LLC, a limited liability company, the sole common member of which is Bayer East Coast LLC and the sole preferred member of which is Bayer HealthCare US Funding LLC. Bayer East Coast LLC's sole member is Bayer US Holding LP, and Bayer HealthCare US Funding LLC's members are Bayer AG, Bayer Pharma AG, and Bayer World Investments B.V. Bayer US Holding LP is a limited partnership in which Bayer World Investments B.V. is the sole General Partner and Bayer Solution B.V. is the sole limited partner. Bayer Solution B.V. is a private company with limited liability organized under the laws of the Netherlands and is wholly-owned by Bayer World Investments B.V. Bayer World Investments B.V. is a private company with limited liability organized under the laws of the Netherlands and is wholly owned by Bayer AG. Bayer AG and Bayer Pharma AG are German Aktiengesellschafts organized under the laws of Germany whose stock is publicly traded in Germany, and their principal places of business are in Germany;
- Dr. Scholl's LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;
- Coppertone LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;

- MiraLAX LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC; and
- Bayer HealthCare US Funding LLC, a limited liability company, whose members are Bayer AG, Bayer Pharma AG, and Bayer World Investments B.V. Bayer AG is a publicly-held German Aktiengesellschaft with its principal place of business in Germany; Bayer Pharma AG is a German Aktiengesellschaft, wholly owned by Bayer AG, with its principal place of business in Germany; and Bayer World Investments B.V. is a private company with limited liability that is wholly owned by Bayer AG.

17. Defendant Bayer Essure Inc. is a Delaware corporation with its principal place of business in New Jersey. Compl. ¶ 6. Accordingly, it is a citizen of Delaware and New Jersey for diversity purposes. *See* 28 U.S.C. § 1332(c).

18. Defendant Bayer HealthCare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in New Jersey. Compl. ¶ 7. Thus, for diversity purposes, it is a citizen of Delaware and New Jersey. *See* 28 U.S.C. § 1332(c).

19. Defendant Bayer AG is a German Aktiengesellschaft whose stock is publicly traded in Germany, and whose principal place of business is in Germany. Compl. ¶ 8. Thus, for diversity purposes, it is a citizen of Germany. *See* 28 U.S.C. § 1332(c).

20. Defendant Bayer Pharma AG is also a German Aktiengesellschaft, wholly owned by Bayer AG, and whose principal place of business is in Germany. Compl. ¶ 9. Thus, for diversity purposes, it is a citizen of Germany. *See* 28 U.S.C. § 1332(c).

21. Defendant Conceptus SAS is a Société par Actions Simplifiée, organized under the laws of France and with its principal place of business in France. Thus, for diversity purposes, it is a citizen of France. *See* 28 U.S.C. § 1332(c).

22. Bayer S.A. is a Sociedade Anônima, organized under the laws of Brazil and with its principal place of business in Brazil. Thus, for diversity purposes, it is a citizen of Brazil. *See* 28 U.S.C. § 1332(c).

23. Plaintiffs allege that they are citizens of Georgia. Compl. ¶¶ 1-2.

24. Because Plaintiffs are citizens of Georgia and the Bayer Defendants are citizens of Delaware, Indiana, New Jersey, Pennsylvania, Brazil, France, and Germany, there is complete diversity, and this Court has jurisdiction under 28 U.S.C. § 1332.

Dated: October 2, 2018

Respectfully submitted,

DECHERT LLP

By: /s/

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Attorneys for Defendants Bayer Corporation, Bayer U.S. LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

I, Christopher Boisvert, do hereby certify that the foregoing document was served upon the following by regular United States mail and e-mail:

T. Matthew Leckman
Leckman Law LLC
527 Bethan Road
Elkins Park, PA 19027
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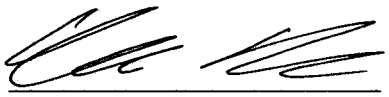

Christopher Boisvert

EXHIBIT A

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JENNIFER DAVIS, 8342 Arracourt Way Fort Benning, GA 31905, and BRYAN DAVIS, 8342 Arracourt Way Fort Benning, GA 31905, Husband and Wife, Plaintiffs, vs. BAYER CORP., 100 Bayer Rd. Building 4, Pittsburgh, Allegheny County, PA 15205, and BAYER U.S. LLC, 100 Bayer Road, Pittsburgh, Allegheny County, PA 15205, and BAYER HEALTHCARE LLC., 100 Bayer Blvd., Whippany, NJ 07981, and BAYER ESSURE, INC., 100 Bayer Boulevard, Whippany, NJ 07981, and BAYER HEALTHCARE PHARMACEUTICALS, INC., 100 Bayer Blvd., Whippany, NJ 07981, and BAYER AG, 51368 Leverkusen, Germany, and BAYER PHARMA AG, MüllerstraBe 178 13353 Berlin, Germany, and	COURT OF COMMON PLEAS PHILADELPHIA COUNTY OCTOBER TERM, 2018 NO: JURY TRIAL DEMAND PETITION FOR DAMAGES

CONCEPTUS SAS, Paris la defense, 10 pl de belgique 92250 la garenne colombes France,)
and)
BAYER S.A., Rua Domingos Jorge 1100, 047790900 São Paulo / SP Brazil,)

Defendants.

NOTICE TO DEFEND

NOTICE:

You have been sued in court. If you wish to defend against the claim set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written appearance personally or by attorney, and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in the Complaint or for any other claims or relief requested by the Plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Philadelphia Bar Association
Lawyer Referral and Information Center
1101 Market Street, 10th Floor
Philadelphia, PA 19107

AVISO:

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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COMPLAINT – CIVIL ACTION
PRODUCT LIABILITY

Plaintiffs, by and through undersigned counsel, file this Complaint against Defendants, Bayer Corporation, Bayer U.S. LLC, Bayer HealthCare LLC, Bayer Essure®, Inc. (f/k/a Conceptus), Bayer Healthcare Pharmaceuticals, Inc., Bayer AG, Bayer Pharma AG, Conceptus SAS, and Bayer S.A. (Collectively the "Bayer Defendants" or "Defendants" or "Bayer") and in support thereof make the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff is a resident of Virginia.

2. Consortium Plaintiff Husband is a resident of Virginia. (Plaintiffs collectively hereinafter referred to as "Plaintiff" unless otherwise specified).

3. BAYER CORPORATION is a for-profit corporation incorporated in the State of Indiana. At all relevant times, Bayer Corporation's principal office was located at 100 Bayer Rd. Building 4, Pittsburgh, Allegheny County, PA 15205. Bayer Corporation is a wholly-owned subsidiary of Bayer AG. Recently, on or around January 1, 2017, Bayer Corporation changed its principal office to New Jersey. However, Bayer Corporation's officers are located in Pittsburgh, Pennsylvania. Defendant, Bayer Corporation, is currently a citizen of New Jersey and Indiana, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, Bayer Corporation, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

4. BAYER U.S. LLC and/or Bayer U.S. LLC has its principal please of business at 100 Bayer Road, Pittsburgh, Allegheny County, PA 15205, and an address registered with the

Pennsylvania Secretary of State in Dauphin County, PA. Defendant is a citizen of Pennsylvania, either through incorporation in Pennsylvania or through having its principal place of business in Pennsylvania, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, Bayer U.S. LLC and/or BAYER U.S. LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

5. BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the State of Delaware and is a wholly-owned subsidiary of Bayer AG. Defendant, Bayer HealthCare LLC., has a principal office at 100 Bayer Blvd., Whippany, NJ 07981. Defendant, Bayer HealthCare LLC, is a citizen of Delaware, Pennsylvania, New Jersey, Germany, and the Netherlands, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, Bayer HealthCare LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

6. BAYER ESSURE®, INC. (f/k/a CONCEPTUS, INC.) is a for-profit corporation incorporated in the State of Delaware and is a wholly-owned subsidiary of Bayer AG and/or Bayer HealthCare LLC. On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly-owned subsidiary of Bayer HealthCare LLC and/or Bayer AG, and thereafter renamed "Bayer Essure® Inc." For purposes of this Complaint, Conceptus, Inc. and Bayer Essure® Inc. are one and the same. Bayer Essure® Inc. has a principal office at 100 Bayer Boulevard, Whippany, NJ 07981. Defendant, Bayer Essure® Inc., is a citizen of Delaware and New Jersey, and is authorized to do and does

business throughout the Commonwealth of Pennsylvania. Defendant, Bayer Essure® Inc., is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

7. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the State of Delaware and is a wholly-owned subsidiary of Bayer AG. Defendant Bayer HealthCare Pharmaceuticals, Inc., has a principal office of 100 Bayer Blvd., Whippany, NJ 07981. Defendant, Bayer Healthcare Pharmaceuticals, Inc., is a citizen of Delaware and New Jersey, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, Bayer Healthcare Pharmaceuticals, Inc., is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

8. BAYER AG is a publicly-held German Aktiengesellschaft, with its principal place of business in Germany. At all relevant times, Bayer AG and one or more of its groups or divisions has been engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Essure® device.

9. BAYER PHARMA AG is a publicly-held German Aktiengesellschaft, with its principal place of business in Germany. Bayer Pharma AG is a wholly-owned subsidiary of Bayer AG. At all times relevant, Bayer Pharma AG and one or more of its groups or divisions has been engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, processing and/or storing adverse events and/or

complaints, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Essure® device.

10. CONCEPTUS SAS is a for-profit corporation with its principal place of business in France. Conceptus SAS is a wholly-owned subsidiary of Bayer AG and/or Bayer HealthCare LLC. At all times relevant, Conceptus SAS and one or more of its groups or divisions has been engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the Essure® device. Conceptus SAS was the "primary international partner of Conceptus, Inc.", and was bought by Conceptus, Inc., prior to its acquisition by Bayer.[1] Conceptus SAS is wholly owned by Bayer A.G.[2], and is also engaged in the processing, storage, and reporting of adverse events and/or complaints related to Essure®.

11. BAYER S.A. is a for-profit corporation with its principal place of business in Brazil and is a wholly-owned subsidiary of Bayer AG. At all times relevant, Bayer S.A. and one or more of its groups or divisions has been engaged in the business of distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the Essure® device. BAYER S.A. is a foreign Bayer entity, wholly owned by Bayer A.G., and engaged in pharmacovigilance activities, including but not limited to the processing, storage, and reporting of adverse events and/or complaints related to Essure®.

[1] *See* SEC Report regarding Conceptus SAS acquisition, available at https://www.sec.gov/Archives/edgar/data/896778/000110465907015543/a07-6962_1ex99d1.htm (last visited January 31, 2018).
[2] *See* list of subsidiaries on Bayer's 2016 Annual Report, available at https://www.bayer.com/en/asm-2017-subsidiary-and-affiliated-companies-bayer-group.pdfx (last visited January 31, 2018).

12. Defendants Bayer Corporation, Bayer U.S. LLC, Bayer HealthCare LLC, Bayer Essure®, Inc. (f/k/a Conceptus), Bayer Healthcare Pharmaceuticals, Inc., Bayer AG, Bayer Pharma AG, Conceptus SAS, and Bayer S.A. are hereafter collectively referred to as "Bayer," or "Defendants," or the "Bayer Defendants."

13. At all relevant times herein mentioned, Bayer authorized and directed and/or participated in the promotion and sale of Essure®, when they knew, or with the exercise of reasonable care should have known, of the increased risks, hazards, and unreasonable dangerous propensities, and thereby actively participated in the tortious conduct which resulted in the serious injuries to the Plaintiff described herein.

14. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between the certain Defendants and other Defendants such that any individuality and separateness between them has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and/or would promote injustice.

15. At all times herein mentioned, the Bayer Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the Essure® device, and processing, reporting, and storing adverse events related to the device. These products were for use by the Plaintiff and Plaintiff's physicians. As such, each

of the Bayer Defendants are individually, as well as jointly and severally, liable to the Plaintiff for their damages.

16. The harm caused to Plaintiff resulted from the conduct of one or various combinations of the Defendants, and through no fault of Plaintiff. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one, or which combination of, the Defendants caused Plaintiff's injuries.

17. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiff.

JURISDICTION AND VENUE

18. This Court has personal jurisdiction, pursuant to 42 Pa.C.S. § 5301 et seq., over the Defendants because, at all relevant times, they have engaged in continuous and substantial business activities in the Commonwealth of Pennsylvania.

19. This court has general personal jurisdiction because the U.S. Headquarters for the parent Bayer entity, Bayer AG, and Bayer Pharma AG, is located in Pittsburgh, Pennsylvania.[3]

20. Further, during all relevant times, Bayer Corporation was held out as the "US headquarters of pharmaceuticals and materials giant Bayer AG," which oversaw "The US subsidiaries of Bayer's three global divisions: Bayer Healthcare (pharmaceuticals, animal health, and over-the counter medicines), MaterialScience (plastics, coatings and polyurethanes), and Bayer CropScience (herbicides, fungicides and insecticides)." At all relevant times, Bayer Corporation was located at 100 Bayer Rd., Pittsburgh, PA 15205.

[3] *See* "HQ" designation at Pittsburgh, Pennsylvania location, http://www.bayer.us/en/contact-us/ (last updated November 24, 2017) (last visited January 28, 2018).

21. As alleged in throughout, the Bayer entities herein are unitary, so that jurisdiction over the parent would draw jurisdiction over the subsidiaries.

22. Defendants engaged in conduct in the Commonwealth of Pennsylvania that was so "continuous and systematic" as to render them "at home" in the forum state, including but not limited to business, marketing, regulatory and research activities.

23. Defendant, Bayer HealthCare LLC, is a citizen of Pennsylvania.

24. Defendant BAYER U.S. LLC / Bayer U.S. LLC has its principal office in Pittsburgh, Pennsylvania.

25. At all times relevant, Defendants were engaged in the business of designing, researching, developing, testing, licensing, manufacturing, marketing, advertising, promoting, selling, distributing, and/or introducing into interstate commerce throughout the United States, which necessarily includes the Commonwealth of Pennsylvania, and Philadelphia, either directly or indirectly through third parties, subsidiaries or related entities, the Essure® device.

26. Furthermore, key officers and employees of the Bayer Defendants are located in Pennsylvania, including but not limited to Keith Abrams, who is an officer of Bayer Corporation, manager of Bayer U.S. LLC, and Assistant Secretary of Bayer Essure, Inc., Bayer HealthCare Pharmaceuticals, Inc., and Bayer HealthCare LLC.[4]

a. Helmut Hegger, President of Bayer Business and Technology Services LLC (BBTS), is located in Pennsylvania.[5] BBTS is listed with the Pennsylvania Secretary of State as a prior name to Bayer U.S. LLC, which now (as of January 2017) maintains employees from multiple Bayer entities, including Defendants Bayer Essure, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals.

[4] *See* https://www.corporationwiki.com/Pennsylvania/Pittsburgh/keith-r-abrams-P7498713.aspx (last visited January 29, 2018); *and* https://www.americanconference.com/speakers/mr-keith-abrams/ (last visited January 29, 2018).
[5] *See* http://www.bayer.us/en/about-bayer/leadership/helmut-hegger/ (last updated August 18, 2017).

b. Also, Dan Cella, the treasurer for Bayer AG, is located in Pennsylvania.[6]

c. Bayer Corporation maintains officers in Pennsylvania, including: Jon R. Wyne, Treasurer; Klaus H. Risse, President; Melvyn A. Silver, Vice President; and Stephen B. Paige, Secretary.[7]

27. There is also "specific" personal jurisdiction, because Defendants used the Commonwealth of Pennsylvania to develop, create a marketing strategy for, label, and/or work on the regulatory approval for Essure®, and all of the Plaintiff's claims arise out of or relate to the Defendants' contacts with Pennsylvania.

28. For example, at all relevant times, Bayer AG and Bayer Pharma AG were headquartered in Pittsburgh, PA, and regulatory activities such as due diligence, postmarket integration activities, and postmarket safety surveillance were conducted by these entities.

a. Pennsylvania was the site of clinical studies regarding Essure®.

i. Pennsylvania was a site of the ESS305 Post-Approval Study, whose purpose was to document the bilateral placement of the ESS305 model. The data obtained from this study was intended to be used to update labeling and training procedures.[8]

ii. Pennsylvania was also a site for the ESS-NSPAS Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test.[9]

b. Ben Zhang, located in Pennsylvania, was the "Head of Business Transformation and Change Management" from 2009-2015, where he was responsible for overseeing a consultant team, team management, development and training, recruiting, and business development. He also served as "Interim Head of Consumer Relations" where he was responsible for "resolution of product liability, adverse event and crisis management issues."[10] Additionally,

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[6] *See* January 23, 2018 FEC filing available at http://docquery.fec.gov/pdf/531/201801239090524531/201801239090524531.pdf#navpanes=0.
[7] *See* https://www.corporations.pa.gov/Search/CorpSearch (last visited February 8, 2018).
[8] *See* Clinical Data Final Report: Ess305 Post-Approval Study, located at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm413805.pdf (last visited January 29, 2018).
[9] *See* https://clinicaltrials.gov/ct2/show/study/NCT01740687?show_locs=Y#contacts (last visited January 29, 2018).
[10] *See* Linkedin page for Ben Zhang, available at https:www.linkedin.com/in/benzhang2009/.

Mr. Zhang was on the HealthCare Management Board, where he "[s]upported commercial due diligence and led the post-merger integration for Bayer's $1.1bn Conceptus acquisition."[11]

c. Further, Bayer HealthCare LLC, which is a citizen of Pennsylvania, is and was at all relevant times, responsible for the manufacturing of Essure®.

d. Bayer Corporation was, at all relevant times, responsible for the finance administration of Essure®.

e. Defendants and their agents, located in Pennsylvania, were involved with the acquisition of Conceptus by Bayer AG.

f. The Bayer Defendants also conducted sales and marketing activities in Pennsylvania, including but not limited to those activities conducted through sales representatives such as Matthew Hladek and Monica Anderson.

i. Additionally, Pennsylvania was home to Key Opinion Leaders, or "KOLs" for Bayer, including Carl R. Della Badia, D.O. of Drexel University – College of Medicine in Philadelphia, Pennsylvania. Dr. Della Badia was a 2008 member of the Speaker's Bureau for Conceptus, Inc.[12] Larry R. Glazerman, M.D., MBA of Mainline Health System in Wynnewood, Pennsylvania, was also a member.[13] Further, Dr. John Roizin was a KOL for Bayer, and received payments for Essure®.[14]

29. At all relevant times, the Bayer Defendants transacted, solicited, and conducted business in Pennsylvania through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Pennsylvania, and committed torts in whole or in part against Plaintiff in Pennsylvania including but not limited to negligent and wrongful conduct in connection with the design, development, testing, promoting, marketing, distribution, labeling and/or sale of Essure®.

30. Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

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[11] *Id*.
[12] *See* https://www.aagl.org/files/08FinalProgram_No%20Ads.pdf (last visited January 28, 2018).
[13] *See* https://www.aagl.org/2012syllabus/12FinalProgram.pdf.
[14] *See* payments made on behalf of Bayer to Dr. Roizin at http://doctors.healthgrove.com/l/610867/John-Roizin-in-Bethlehem-Pennsylvania#Open%20Payments&s=2GU8tV (last visited January 29, 2018).

31. Further, jurisdiction is proper under 28 U.S.C.A. § 1441 (b) ("A civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in this interest properly joined and served as Defendants is a citizen of the State in which such action was brought.").

32. Venue is proper in this Court, pursuant to Pa. R. Civ. P. 1006 and 2179, as Pennsylvania is where the Bayer Defendants have their principal place of business and/or where they regularly conduct business; where Plaintiff's causes of action arose, and/or where a transaction or occurrence took place out of which this cause of action arose.

33. The Plaintiff herein is properly joined in this action pursuant to Pa. R. Civ. P. 2229(a) as they assert a right to relief under the same transaction, occurrence, or series of transactions or occurrences, and a question of law or fact is common to all Defendants in the action.

INTRODUCTION

34. This Complaint is brought by Plaintiff who was implanted with a female birth control device, known as "Essure." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in reality, the device migrates from the tubes, perforates organs, breaks into pieces, and/or corrodes wreaking havoc on the female body.

35. As a result of (1) Defendants' negligence described *infra* and (2) Plaintiff's reliance on Defendants' warranties and representations, Defendants' Essure device migrated/fractured and/or punctured internal organs.

36. Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, Essure became "adulterated" and "misbranded", pursuant to (1) the FDA due to Defendants' failure to conform with the FDA requirements prescribed in the CPMA and (2) violations of Federal Statutes and Regulations noted *infra.*

37. Pursuant to Defendants' CPMA (which reads: "Failure to comply with conditions of approval invalidates this approval order"), the C.F.R, and the Federal Food, Drug and Cosmetic Act ("FD&C Act"): the product is "adulterated" and "misbranded" and thus, could not have been marketed or sold to Plaintiff.

38. Specifically, Essure was adulterated and misbranded as Defendants (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with Federal laws regarding marketing and distribution as specifically described *infra.*

39. The fact that Defendants failed to comply with these conditions is not a mere allegation made by Plaintiff. These failures to comply with both the CPMA and Federal regulations are memorialized in several FDA findings, including Notices of Violations and Form 483's issued by the FDA.

40. As discussed in greater detail *infra*, Defendants were cited by the FDA and the Department of Health for:

(a) failing to report and actively concealing 8 perforations which occurred as a result of Essure;

(b) erroneously using non-conforming material in the manufacturing of Essure;

(c) failing to use pre-sterile and post-sterile cages;

(d) manufacturing Essure at an unlicensed facility; and

(e) manufacturing Essure for three years without a license to do so.

41. Defendants were also found, by the FDA, to be:

(a) Not reporting … complaints in which their product migrated;

(b) Not reporting to the FDA incidents of bowel perforation, Essure coils breaking into pieces and migrating out of the fallopian tubes;

(c) Only disclosing 22 perforations while having knowledge of 144 perforations;

(d) Not considering these complaints in their risk analysis for the design of Essure;

(e) Failing to have a complete risk analysis for Essure;

(f) Failing to analyze or identify existing and potential causes of non-confirming product and other quality problems;

(g) Failing to track the non-conforming product;

(h) Failing to follow procedures used to control products which did not confirm to specifications;

(i) Failing to have complete Design Failure Analysis;

(j) Failing to document CAPA activities for a supplier corrective action;

(k) Failing to disclose 16,047 complaints to the FDA as MDR's (Medical Device reports which are suspected from device malfunction or associated with injury); and

(l) Failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two year report schedules.

42. Most egregiously, on May 30, 2013, the FDA uncovered an internal excel spreadsheet with 16,047 entries for complaints which were not properly reported to the FDA. Here, Defendant did not disclose to the FDA complaints where its product migrated outside of the fallopian tube. Defendants excuse was that those complaints were not reported because the patients were "not –at last contact- experiencing pain….and were mere trivial damage that does

not rise to the level of a serious injury." Accordingly, the FDA again warned Defendants for violations of the FD&C Act.

43. As a result, the "adulterated" and "misbranded" product, Essure, which was implanted in Plaintiff should never have been marketed or sold to Plaintiff pursuant to Federal law.

44. Lastly, Defendants concealed and altered the medical records of its own trial participants to reflect favorable data. Specifically, Defendants altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process. Subsequently, Defendants failed to disclose this and concealed it from Plaintiff and their implanting physicians.

45. Plaintiff's causes of action are all based on deviations from the requirements in the CPMA and/or violations of Federal statutes and regulations.

46. Plaintiff's causes of action are also based entirely on the express warranties, misrepresentations, and deceptive conduct of Defendants, which were relied upon by Plaintiff prior to having the device implanted. Under Pennsylvania law, Plaintiff's claims for breach of express warranties are not preempted by the Medical Device Act ("MDA").

47. In addition, Defendants failed to comply with the following express conditions and Federal regulations:

(a) "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(b) "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(c) Report Due Dates- six month, one year, eighteenth month, and two year reports.

(d) A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

(e) Effectiveness of Essure is established by annually reporting on the 745 women who took place in the clinical tests.

(f) Successful bilateral placement of Essure is documented for newly trained physicians.

(g) Warranties are truthful, accurate, and not misleading.

(h) Warranties are consistent with applicable Federal and State law.

48. These violations rendered the product "adulterated" and "misbranded"- precluding Defendants from marketing or selling Essure per the FDA, and, more importantly endangered the lives of Plaintiff and hundreds of thousands of women.

49. Defendants actively concealed these violations and never advised Plaintiff of the same. Had Plaintiff known that Defendants were concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license to do the same, they never would have had Essure implanted.

DESCRIPTION OF ESSURE AND HOW IT WORKS

50. Essure is a permanent form of female birth control (female sterilization). The device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage.

51. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use.

52. The micro-inserts are comprised of two metal coils which are placed in a woman's fallopian tubes via Defendants' disposable delivery system and under hysteroscopic guidance (camera).

53. The hysteroscopic equipment needed to place Essure was manufactured by a third party, is not a part of Defendants' CPMA, and is not a part of Essure. However, because Plaintiff's implanting physicians did not have such equipment, Defendants provided it so that it could sell Essure.

54. The coils are comprised of nickel, steel, nitinol, and PET fibers. In other words, the coils are metal-on-metal.

55. Defendants' disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are allowed to visualize this complicated process through the hysteroscopic equipment provided by Defendants.

56. After placement of the coils in the fallopian tubes by Defendants' disposable delivery system, the micro-inserts expand upon release and are intended to anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

57. The coils are alleged to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

58. After three months following the device being implanted, patients are to receive a "Confirmation" test to determine that the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpinogram ("HSG Test" or "Confirmation Test").

59. Regardless of the Confirmation Test, Defendants warrant that Essure allows for visual confirmation of each insert's proper placement during the procedure.

60. Essure was designed, manufactured, and marketed to be used by the average gynecologists throughout the world, as a "quick and easy" and "non-surgical" outpatient procedure to be done without anesthesia.

EVOLUTION OF ESSURE

61. Essure was first designed and manufactured by Conceptus, Inc. ("Conceptus").

62. Conceptus and Defendants merged on or about April 28, 2013.

63. For purposes of this lawsuit, Conceptus and Defendants are one in the same.

64. Essure, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendants.

65. Defendants also trained physicians on how to use its device and other hysteroscopic equipment, including Plaintiff's implanting physicians.

66. Prior to the merger between Conceptus and Bayer defendants, Conceptus obtained CPMA for Essure.

67. By way of background, Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are

of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

68. PMA is intended to be a stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA.

69. An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device- assuming it complies with federal laws, any CPMA order and is not "adulterated" or "misbranded."

70. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission.

71. However, the PMA process for Essure was "expedited" and several trial candidates' medical records were altered to reflect favorable data.

72. According to the FDA, a class III device that fails to meet CPMA requirements is considered to be adulterated under section 501(f) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.

73. Regarding the Premarket Approval Process, devices can either be "approved," "conditionally approved," or "not approved."

74. Essure was "conditionally approved" or in other words, had only CPMA not outright PMA, the "gold standard."

75. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval invalidates this approval order[15]." The following were conditions of approval:

(a) "Effectiveness of Essure is established by annually reporting on the 745 women who took part in clinical tests."

(b) "Successful bilateral placement of Essure is documented for newly trained physicians."

(c) "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(d) "Report to the FDA whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(e) Effectiveness of Essure is established by annually reporting on the 745 women who took place in the clinical tests.

(f) Successful bilateral placement of Essure is documented for newly trained physicians.

(g) Warranties are truthful, accurate, and not misleading.

(h) Warranties are consistent with applicable Federal and State law.

(i) Conduct a post approval study in the US to document the bilateral placement rate for newly trained physicians.

(j) Include results from the annual reporting on the patients who took part in the Pivotal and Phase II clinical investigations in the labeling as these data become available.

(k) Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device facilitates, necessitate a labeling, manufacturing, or device modification.

(l) Submit a PMA supplement whenever there are changes to the performance of the device.

[15] Note: The CPMA order does not read…failure to comply *may* invalidate the order.

REQUIREMENTS UNDER FEDERAL REGULATIONS

76. The CPMA also required Defendants to comply with the Medical Device Reporting regulations and post market requirements for Class III medical devices:

(a) report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury;

(b) report to the FDA within thirty (30) days whenever they receive notice of serious injury;

(c) report to the FDA information suggesting that one of the Manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;

(d) monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

(e) submit a PMA Supplement for any change in Manufacturing Site, 21 CFR §§ 814.39 et seq.;

(f) establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;

(g) establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 CFR §§ 820.30 et seq.

(h) document all Corrective Action and Preventative Actions taken by the Manufacturer to address non-conformance and other internal quality control issues, 21 CFR §§ 820.100 et seq.

(i) establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.

(j) establish Quality Management System (QMS) procedures to assess potential causes of non-conforming products and other quality problems, 21 CFR §§820.70 et seq. and 21 CFR §§ 27 820.90 et seq.

(k) report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80

(l) advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

77. Defendants were also at all times responsible for maintaining the labeling of Essure. Accordingly, Defendants had the ability to file a "Special PMA Supplement – Changes Being Effected" ("CBE") which allows Defendants to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

(a) labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

(b) labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

(c) labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

(d) changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

78. Upon obtaining knowledge of these potential device failure modes, the Defendants were required under the Essure CPMA, 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq. and the FDA Recognized Consensus Standard ISO 14971 to use this information to routinely update the risk analyses for the Essure device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendants were required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

FAILURES OF DEVICE

79. After obtaining the CPMA, Defendants became aware of potential quality and failure modes associated with Essure and failed to warn Plaintiff and/or their implanting physicians. Defendants became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

(a) the stainless steel used in Essure can become un-passivated, which allows it to rust and degrade;

(b) the nitinol could have a nickel rich oxide, which the body attacks;

(c) the "no lead" solder could in fact have trace lead in it;

(d) the Galvanic action between the metals used to manufacture Essure, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;

(e) the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

(f) latent manufacturing defects, such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may exist in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

(g) degradation products of PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues and

(h) the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body.

VIOLATIONS OF FEDERAL REQUIREMENTS

80. In June 2002, the FDA found the following objectionable conditions:

(a) Design outputs were not completely identified.

(b) Corrective and preventative action activities were not being documented, including implementation of corrective and preventative actions.

(c) Procedures addressing verification of corrective preventative actions were not implemented.

81. In July 2002, during an inspection of Defendants facility, the FDA observed that adverse events were not captured in the data.

82. In June 2003, the following observations were made by the FDA which resulted in Form 483s:

(a) Two lot history records showed rejected raw materials which was not documented and therefore could not be tracked.

(b) Procedures were not followed for the control of products that did not conform to specifications.

83. In July of 2002, the FDA found that:

(a) Defendant "does not have an assurance/quality control unit.

84. In December 2010, the FDA found that Defendants were "not reporting complaints of their product being seen radiographically in the patient's abdominal cavity" and "did not have a risk analysis of the coils being in the abdominal cavity."

85. Defendants failed to comply with *several* conditions:

(a) Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month and two year reports. All reports failed to meet the respective deadlines.

(b) Defendants failed to document successful placement of Essure concealing the failure rates.

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report 8 perforations which occurred as a result of Essure and was cited for the same by the FDA via Form 483.[16]

[16] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

(d) Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendants failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483.

(e) As outlined *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

(f) Defendants' warranties were not consistent with applicable Federal and State law.

(g) Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints.

86. Defendants also were found to be:

(a) erroneously using non-conforming material in the manufacturing of Essure and not tracking where it went;

(b) failing to use pre-sterile and post-sterile cages;

(c) manufacturing Essure at an unlicensed facility;

(d) manufacturing Essure for three years without a license to do so.

(e) Not reporting … complaints in which their product migrated;

(f) Not considering these complaints in their risk analysis for the design of Essure;

(g) Failing to document CAPA activities for a supplier corrective action;

87. Specifically,

(a) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

(b) Defendants had notice of 168 perforations but only disclosed 22 to the FDA.

(c) On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

(d) On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented.

(e) On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went) .

(f) On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

88. In response Defendants admitted that "the device may have caused or contributed to a death or serious injury, and an MDR Report is required to be submitted to FDA."

89. In addition, Defendants' failure to timely file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from the more than 32,000 complaints it received, violated the CPMA, FDA post-marketing regulations, and parallel state law.

90. Moreover, Defendants did not provide the requisite training to the implanting physicians prior to selling it to the same.

FDA HEARINGS AND RESULTING ACTION

91. The Defendants conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because the Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure device, the public's knowledge of the risks associated with the Essure device were seriously hampered and delayed. This endangered patient safety, including Plaintiff's safety.

92. As the FDA continued to force Defendants to provide additional information known to them that had been withheld, more information belatedly was made known to the medical community, including information concerning the frequency, severity and permanence of complications associated with the prescription and implementation of the Essure device.

93. This belated and untimely release of relevant and important information lead to an increasing number of adverse events being reported to the FDA about Essure from patients and physicians. Because of these complaints, the FDA convened a public hearing concerning the safety and efficacy of the Essure device. At that hearing, Defendants continued to misrepresent the safety and efficacy of Essure:

(a) the efficacy rates for Essure are 99.6%; in reality, studies show that the chances of becoming pregnant with Essure are higher than with tubal ligations and higher than the rates reported by Bayer to the FDA at the public hearing;

(b) Defendants testified that skin patch testing is not a reliable predictor of clinically significant reactions to nickel-containing implantable devices, including Essure. Despite this, Bayer told physicians and patients that a nickel sensitivity test was sufficient to determine whether a patient was a suitable candidate for an Essure device

(c) Defendants testified that "[a]s an alternative to Essure, laparoscopic tubal ligation is a safe and effective method of permanent birth control." In reality, studies show that the chances of becoming pregnant with Essure are higher than with tubal ligations, and Essure patients are much more likely to require additional surgeries to correct complications associated with the sterilization procedure.

(d) Defendants testified that most of the reports of adverse events to the FDA have come from consumers and not Defendants, which is unusual. In reality, Defendants failed to report thousands of complaints of adverse events that it had received.

94. On February 29, 2016, the FDA first publicly announced "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device. The FDA took the following actions:

(a) The FDA is requiring a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device."

(b) The FDA is requiring Defendants to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure. The FDA's draft Patient Decision Checklist is a five-page document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ('perforation'), or movement of the device into the abdomen or pelvis ('intra-peritoneal migration')"; "allergy or hypersensitivity reactions"; symptoms such as changes in skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that "there is no reliable test to predict ahead of time who may develop a reaction to the

device"; the possibility that the Essure device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure device has to be removed after placement, it will require surgery to remove and possibly a hysterectomy.

(c) The FDA has also ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's quality of life. . . .The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

95. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Plaintiff of the true risks of Essure. Had the Defendants complied with their federal regulatory duties and their duties under state law by reporting the known risks and complications in a timely fashion, the Plaintiff and their physicians would have had this relevant, critical information available to them prior to the implant of the Essure device. At all relevant times, Defendants' Essure product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants. Moreover, Defendants misrepresentations regarding Essure discussed *infra*, in effect, over promoted Essure and nullified otherwise adequate warnings.

96. Lastly, although Essure appears at first glance to be a "medical device," Defendants actually categorize it as a "drug."

97. In short, (1) Essure is considered an "adulterated" and "misbranded" product that could not have been marketed or sold to Plaintiff per the FDA and Federal law and (2) all of

Plaintiff's claims center around violations of the CPMA requirements and/or Federal regulations and statutes.

DEFENDANTS' TRAINING AND DISTRIBUTION PLAN

98. Defendants (1) failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physicians; (2) provided specialized hysteroscopic equipment to the implanting physicians who was not qualified or competent to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiff's safety and well-being.

99. Because Essure was the first device of its kind, the implanting physicians was trained by Defendants on how to properly insert the micro-inserts using the disposable delivery system and was given hysteroscopic equipment by Defendants.

100. In order to capture the market, Defendants independently undertook a duty of training physicians outside of FDA guidelines, including the implanting physicians, on how to properly use (1) its own mechanism of delivery and (2) the specialized hysteroscopic equipment manufactured by a third party.

101. Regarding Essure, Defendants' Senior Director of Global Professional Education, stated, "training is the key factor when clinicians choose a new procedure" and "For the Essure procedure, the patient is not under anesthesia, therefore a skilled approach is crucial."

102. In fact, because gynecologists and Plaintiff's implanting physicians were unfamiliar with the device and how to deliver it, Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created

Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures."

103. Defendants provided no training to the implanting physicians on how *to remove* Essure should it fail.

104. Defendants also kept training records on all physicians "signed-off to perform Essure procedures."

105. In order to sell its product and because the implanting physicians did not have access to the expensive hysteroscopic equipment, Defendants provided the implanting physicians with hysteroscopic equipment which, although is not a part of Essure, is needed to implant Essure. The entrustment of this equipment is not part of any CPMA.

106. In fact, Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc. (1) to obtain specialized hysteroscopic equipment to then give to physicians and (2) to increase its sales force to promote Essure.

107. According to Defendants, these agreements allowed Defendants to "gain market presence…and expand … market opportunity by driving adoption among a group of physicians."

108. In regard to the entrustment of such specialized equipment, Defendants admitted: "We cannot be certain how successful these programs will be, if at all." *See US SEC Form 10-Q: Quarterly Report Pursuant to Section 13 or 15(d)of the SEC Act of 1934.*

109. Defendants "handed out" this hysteroscopic equipment to unqualified physicians, including Plaintiff's implanting physicians, in an effort to sell its product.

110. Defendants knew or failed to recognize that the implanting physicians were not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physician in order to capture the market.

111. In return for providing the expensive hysteroscopic equipment, Defendants required that the implanting physicians purchase two Essure "kits" per month. This was a part of Defendants' unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff.

112. Defendants' distribution plan included requiring the implanting physicians to purchase two (2) Essure "kits" per month, regardless of whether they were used or not. This distribution plan created an environment which induced the implanting physicians to "push" Essure and implant the same into Plaintiff.

113. In short, Defendants used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as "bait." Once the implanting physicians "took the bait" they were required to purchase two (2) Essure "kits" per month, regardless of whether they sold any Essure "kits".

114. This was an unreasonably dangerous distribution scheme as it compelled the implanting physicians to sell two (2) devices per month at the expense of Plaintiff's safety and well-being.

115. Defendant's distribution plan also included (1) negligently distributing Essure in violation of FDA orders and Federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (4) failing to report and actively concealing adverse events which occurred as

a result of Essure; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure at an unlicensed facility and (8) manufacturing Essure for three years without a license to do so.

116. In short, Defendants (1) failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physicians; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (3) created an unreasonably dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

117. All of this was done in violation of Federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiff's safety.

PLAINTIFF'S HISTORY

118. Plaintiff Jennifer Davis is a resident of Georgia. She was implanted with Essure on or about 2010. As a result of Essure, Plaintiff suffered from severe and permanent injuries, including, *inter alia*, pain and suffering and emotional distress. Plaintiff HUSBAND suffered a loss of consortium.

FRAUDULENT CONCEALMENT/DISCOVERY RULE/EQUITABLE TOLLING/EQUITABLE ESTOPPEL

SUMMARY OF ACTIVE CONCEALMENT

119. First, Defendants' fraudulent acts and/or omissions discussed below, before, during and/or after the acts causing Plaintiff's injuries, prevented Plaintiff and/or Plaintiff's physicians from discovering the injuries or causes thereof as alleged in this complaint until Spring, 2018.

120. Second, Defendants' failure to report, document, or follow up on the known adverse event complaints, and concealment and altering of adverse events, serious increased risks, dangers, and complications, constitutes fraudulent concealment that tolls Plaintiff's statute of limitations.

121. Third, and in the alternative, Defendants are also estopped from relying on any statute of limitations defense because it continued to refute and deny reports and studies questioning the safety of Essure, actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and the Plaintiff. As a result of Defendants' concealment of the true character, quality, history, and nature of their product, they are estopped from relying on any statute of limitations defense.

122. Defendants furthered their fraudulent concealment through act and omission, including misrepresenting known dangers and/or defects in Essure and/or arising out of the use of Essure and a continued and intentional, systematic failure to disclose and/or conceal such information from/to the Plaintiff, Plaintiff's physicians, and the FDA.

123. In short, Defendants:

(a) Actively and intentionally concealed from Plaintiff that their physicians were not trained pursuant to the FDA-approved training noted *infra*.

(b) Actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, and

failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and the Plaintiff.

(c) Actively and intentionally concealed from Plaintiff and Plaintiff's physician's risks by making the misrepresentations/warranties noted *infra* knowing they were false. In short, Defendants knew the misrepresentations were false because they had studies and reports which showed the opposite yet altered and concealed the same from Plaintiff, the FDA and Plaintiff's physicians. Defendants made the misrepresentations with the intent of misleading Plaintiff into relying on them because they had studies and reports which showed the opposite yet decided to conceal the same (collectively "the acts and omissions")

124. If Defendants had met their duties under the above mentioned federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiff and Plaintiff's physicians of the increased risks and serious dangers associated with Essure in time to have lessened or prevented Plaintiff's injuries, which is evidenced by the fact that the FDA is now mandating a new clinical trial, a "black box" warning, and a "patient decision checklist" which discuss and warn in detail, the risks of the very same injuries Plaintiff suffered and Defendants concealed and altered. Had Defendants satisfied their obligations, these FDA mandates would have been plausible prior to Plaintiff's implantation. As discussed *infra*, Defendants continued to misrepresent the safety and efficacy of Essure at the FDA Hearings.

125. In short, Defendants manipulated its reports to the FDA and presented false and misleading information, which, in turn, caused or contributed to Plaintiff's consent not being

informed as critical facts regarding the nature and quality of side effects from Essure were concealed from Plaintiff and their physicians.

126. Defendants did this in an effort to maintain the impression that the Essure device had a positive risk/benefit profile, to guard sales, and to ensure that Plaintiff and their physicians did not have the salient facts in order to bring the claims alleged in this amended complaint.

127. Defendants' conduct was malicious, intentional, and outrageous, and constitutes a willful and wanton disregard for the rights and safety of Plaintiff and others.

FDA CALLS ESSURE MEETING

128. The FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and plan recommendations for the Essure device.

129. In April, 2018 the FDA first announced that it would force a major change to the Essure warning label and also require all women considering Essure, and their implanting physicians, fill out a "Patient Decision Checklist," or Risk Acknowledgement Form, to ensure that they are fully informed of the true risks.[17]

130. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.[18]

131. The new warning and checklist changed the risk/benefit profile of Essure for Plaintiff and gave rise to new salient facts which Plaintiff and her physicians did not and could not have had prior to Spring, 2018.

132. This patient decision checklist requires a patient's signature and doctor's signature, recognizing new risks previously not disclosed.

[17] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm.
[18] *Id.*

133. Finally, women considering the device will have the chance to be fully informed of its true risks.

134. This result is why Defendants withheld and actively concealed safety information from the FDA and the public for years.

135. Upon information and belief, Defendants knew that if the true risks of Essure were known to the FDA, then they should or would inevitably be communicated to physicians and Plaintiff.

136. The checklist specifically warns of device migration, perforation of organs, and new side effects that Defendants had been cited for hiding from the FDA, Plaintiff, and Plaintiff's physicians and/or enhances the sufficiency of the same.

137. The checklist enhances the sufficiency of the warnings given to potential Essure patients and completely alters the process of undergoing the procedure.

138. The checklist has a major impact on the risk/benefit profile of the device, and Plaintiff would not have had the device implanted with it in place.

139. On February 29, 2016, the FDA announced that it would require a detailed boxed warning for the Essure device. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events. Boxed warnings indicate the highest level of risk.

140. The FDA suggested the following warning:

> **WARNING: Some patients implanted with the Essure System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization**

with the Essure device during discussion of the benefits and risks of the device.[19]

141. This boxed warning directly addresses side effects that Defendants had been cited for hiding from the FDA and the public for years.

DISCOVERY RULE- TOLLING

142. Plaintiff did not know of the claims and their underlying facts asserted in this amended complaint, nor could any reasonable prudent person know of such claims until Spring, 2018.

143. Plaintiff did not possess the sufficient critical facts to put her on notice that the wrongs and the acts and omissions had been committed until such date. This is because it was not until an FDA hearing that Essure's safety and Defendants' acts and omissions were publicly called into question by the FDA and the medical community and the FDA required the "black box warning," "patient decision checklist," and "new clinical trials."

144. In fact, no reasonable person in Plaintiff's position would have been aware of the salient facts of this complaint until after Spring, 2018.

145. Plaintiff did not have the opportunity to discover the harm inflicted because Defendants were and are continuing to conceal the acts and omissions noted above.

146. At all times material hereto, Plaintiff exercised reasonable diligence in investigating potential causes of her injury by discussing her injuries with healthcare providers. None of the conversations gave Plaintiff a reason to suspect, or reasonably should have given Plaintiff a reason to suspect that Essure or Defendants' tortious conduct in this complaint was the cause of such injuries until Spring, 2018.

[19] *FDA Draft Guidance on Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, issued March 4, 2016*

147. Regardless of the exercise of reasonable diligence, Plaintiff did not know or reasonably should not have known that she suffered injury and that her injury had been caused by Defendants' conduct in this complaint until Spring, 2018.

148. Plaintiff neither suspected nor knew of Defendants' wrongdoings as alleged in this complaint until Spring, 2018.

149. In sum, Plaintiff were reasonably unaware, and had no reasonable way of knowing, that their injuries described above were caused by Defendants' conduct as alleged in this complaint until Spring, 2018.

150. As such, Plaintiff's statute of limitations did not begin to run until Spring, 2018.

FRUADULENT CONCEALMENT- EQUITABLE TOLLING

151. Defendants committed affirmative independent acts of concealment (including the acts and omissions) and intentionally mislead Plaintiff as noted above upon which Plaintiff and Plaintiff's physicians relied on.

152. The acts and omissions misled Plaintiff in regard to their causes of action and prevented them from asserting such rights because the facts which would support their causes of action as alleged in this complaint were not apparent to a reasonably prudent person until Spring, 2018.

153. Defendants also prevented Plaintiff from asserting their rights in this complaint by committing affirmative independent acts of concealment as noted above upon which Plaintiff relied on.

154. Due to the acts and omissions of concealment, Plaintiff were not cognizant of the facts supporting their causes of action in this complaint until Spring, 2018.

155. As such, Plaintiff's statute of limitations were tolled in light of Defendants' fraudulent concealment and their statute began to run starting from the date that facts supporting their causes of action in this complaint became apparent or Spring, 2018.

156. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiff and their physicians of vital information essential to the pursuit of the claims in this complaint, without any fault or lack of diligence on their part. Plaintiff relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct.

EQUITABLE ESTOPPEL

157. In the alternative, Defendants are estopped and may not invoke the statute of limitations as through the fraud or concealment noted above, specifically the acts and omissions, Defendants caused the Plaintiff to relax her vigilance and/or deviate from her right of inquiry into the facts as alleged in this complaint.

158. Defendants affirmatively induced Plaintiff to delay bringing this complaint by the acts and omissions.

159. In addition to acts and omissions noted above, Defendants consistently represented to Plaintiff and/or Plaintiff's physicians that Essure was not the cause of any of Plaintiff's injuries to delay her bringing this complaint.

160. Defendants are and were under a continuing duty to monitor and disclose the true character, quality, and nature of Essure. Because of Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendants are estopped from relying on any statute of limitations defense.

FACTS AND WARRANTIES

161. First, Defendants failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physicians, including the implanting physicians, on how to use its device and in hysteroscopy.

162. The skills needed to place the micro-inserts as recognized by the FDA panel in the PMA process "are way beyond the usual gynecologist."

163. Accordingly, Defendants went out and attempted to train the implanting physicians on (1) how to use its device and (2) in hysteroscopy. Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures." Defendants had no experience in training others in hysteroscopy.

164. Defendants failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physicians and provided hysteroscopic equipment to the implanting physicians who was not qualified to use such complicated equipment.

165. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendants' training methods were failing[20].

166. Second, Defendants provided hysteroscopic equipment to the implanting physicians who was not competent to use such device. Defendants knew the implanting

[20] *Learning curve of hysteroscopic placement of tubal sterilization micro inserts*, US National Library of Medicine, Janse, JA.

physicians was not competent to use such sophisticated equipment, yet provided the equipment anyway in order to sell its product.

167. Third, Defendants' distribution plan of requiring the implanting physicians to purchase two (2) Essure kits a month, was an unreasonably dangerous plan as it compelled the implanting physicians to insist that Essure be used in Plaintiff.

168. Defendants' distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and Federal law; (2) the promotion of Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure and failing to keep track of the non-conforming material; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

169. Lastly, Plaintiff relied on several warranties which were given directly by Defendants to Plaintiff, prior to implantation, on the internet and in the implanting physicians' office, through Defendant's website and advertising, as outlined in detail *infra*.

NEGLIGENT TRAINING – COUNT I

170. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

171. First, Defendants undertook an independent duty to train physicians on how to properly use its device to place the micro-inserts which failed to abide by FDA training guidelines.

172. In fact, Defendants (1) created an Essure Training Program; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures."

173. As part of Defendants' training: Defendants had a duty to abide by the FDA training guidelines for the implanting physicians on how to place Essure using its own delivery system, certify the implanting physicians, and oversee this particular procedure. Defendants also had a duty to disclose adverse events to the physicians so that they in turn could properly advise their patients of the actual risks.

174. Specifically, pursuant to the FDA-approved training regulations and guidelines, Defendants had a duty to comply with the following Federal requirements so that implanting physicians performed "competent procedures" and would be able to "manage possible technical issues":

(a) Ensure that the implanting physicians completed the required preceptoring (generally 5 cases) in Essure placement until competency;

(b) Ensure that the implanting physicians had read and understood the Physician Training Manual;

(c) Ensure that the implanting physicians had "successful completion of Essure Simulator Training";

175. As outlined in the Physicians Manual these requirements were necessary in order to:

(a) Ensure that the implanting physicians were selecting appropriate patients from Essure;

(b) Ensure that the implanting physicians were appropriately counseling Plaintiff on the known risks; and

(c) Ensure the implanting physicians were qualified and competent to perform the Essure procedure to ensure proper placement to preclude migration, perforation and fracturing of coils.

176. Defendants breached this duty and parallel state law thereby departing from the FDA-approved guidelines by:

(a) Not ensuring that the implanting physicians completed the required preceptoring in Essure placement until competency. The implanting physicians did not complete the required preceptoring until competency requirement;

(b) Not ensuring that the implanting physicians had read and understood the Physician Training Manual; The Implanting Physicians did not understand the Physician Training Manual.

(c) Not ensuring that the implanting physicians had "successful completion of Essure Simulator Training"; The implanting physicians did not successfully complete the Essure Simulator Training.

177. This departure from the training guidelines caused the Essure coils to migrate/fracture and/or perforate organs because:

(a) The Essure Training Program ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, and/or fracture producing the damages noted above;

(b) The required preceptoring ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, and/or fracture producing the damages noted above;

(c) The requirement to read and understand the Physician Training Manual ensured proper placement, and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, and/or fracture producing the damages noted above;

178. This breach caused Plaintiff's damages noted above.

179. As a result of Defendants' negligence individually, jointly, and severally, Plaintiff sustained the injuries and exacerbations noted above.

180. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

181. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

182. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

183. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENCE- RISK MANAGEMENT– COUNT II

184. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

185. In short, Defendants had a duty under both state and Federal law to have in place a reasonable risk management procedure to ensure, *inter alia*, (1) that adverse reports were being reported to the FDA so that it could be relayed to the implanting physicians and/or Plaintiff; (2) that adverse reports were considered in its risk analysis and that the risk analysis was updated to

reflect the same so that it could be relayed to the implanting physicians and/or Plaintiff; (3) that they investigate information about the risks Essure posed so that it could be relayed to the implanting physicians and/or Plaintiff; (4) that the continued sale of Essure was appropriate and reasonable despite the information being withheld to the public by Defendants (5) monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;(6) establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.; and (7) maintain the labeling of Essure by filing a "Special PMA Supplement – Changes Being Effected" ("CBE") which allows Defendants to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d).

186. Specifically, Defendants had a duty to comply with the following Federal regulations but breached the same regulations by the subsequent violations noted directly below (which Defendants were cited for by the FDA):

(a) 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians. This failing to disclose and include in their risk management analysis was a condition of approval in its CPMA)

(b) 21 C.F.R. 803.1(a)- This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to,

establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow-up. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(c) 21 C.F.R. 803.10- (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.(2) Submit annual reports (described in 803.33) to us.(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or(ii) Submit reports of device-related malfunctions to the manufacturer.(2) [Reserved](c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or(ii) A reportable event for which we made a written request.(3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(d) 21 C.F.R. 803.50(a)- (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise

become aware of information, from any source, that reasonably suggests that a device that you market:(1) May have caused or contributed to a death or serious injury; or(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.(b) What information does FDA consider "reasonably known" to me?(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;(ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(e) 21 C.F.R. 803.53- You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that:(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(f) 21 C.F.R. 806.10- (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:(1) To reduce a risk to health posed by the device; or(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b).(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.(c) The manufacturer or importer shall include the following information in the report:(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a pre-amendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.(9) The total number of devices manufactured or distributed subject to the correction or removal

and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.(10) The date of manufacture or distribution and the device's expiration date or expected life.(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.(12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.(d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.(e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013]

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(g) 21 C.F.R. 814.84-(a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.(b) Unless FDA specifies otherwise, any periodic report shall:(1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b).(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:(i)

Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.(3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter.(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(h) 21 C.F.R. 820.65- Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(Defendants breached this federal standard by failing to establish and maintain procedures for identification of each Essure unit which in turn precluded proper corrective actions and led to the failing to disclose and include in their risk management analysis thousands of adverse events and complaints for migrations, perforations, pregnancies, and device failures and malfunctions, which in turn were never disclosed to Plaintiff and Implanting Physicians. This failing to disclose and include in their risk management analysis was a condition of approval in its CPMA)

(i) 21 C.F.R. 822-Post market surveillance- This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:(a) Failure of the device would be reasonably likely to have serious adverse health consequences;(b) The device is intended to be implanted in the human body for more than 1 year;… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the

collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(Defendants were cited for and breached this federal standard by failing to comply with postmarket surveillance plans. Specifically by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians. Defendants further breached this federal standard by not withdrawing its product from the market.)

(j) 21 C.F.R. 820.180- All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(k) 21 C.F.R. 820.198-(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:(1) All complaints are processed in a uniform and timely manner;(2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be

promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:(1) Whether the device failed to meet specifications;(2) Whether the device was being used for treatment or diagnosis; and(3) The relationship, if any, of the device to the reported incident or adverse event.(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:(1) The name of the device;(2) The date the complaint was received;(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;(4) The name, address, and phone number of the complainant;(5) The nature and details of the complaint;(6) The dates and results of the investigation;(7) Any corrective action taken; and(8) Any reply to the complainant.(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:(1) A location in the United States where the manufacturer's records are regularly kept; or(2) The location of the initial distributor.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(l) FDA requirement in CPMA order- "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(m) FDA requirement in CPMA order- "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of

adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(n) Monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physician.)

(o) Establish internal procedures for reviewing complaints and event reports, 21 CFR §§820.198, §§ 820.100 et seq. and §§ 820.20 et seq.; and

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

187. Due to these breaches, Defendants were cited by the FDA as Defendants "did not consider these complaints in their risk analysis" and "for their risk analysis of Essure being incomplete."

188. This was an unreasonably dangerous and negligent risk analysis plan which was required by Federal law as it put Plaintiff at unnecessary risk of injury due to Defendants' failure to report adverse reports to the FDA, to track non-conforming product, update its labeling of Essure, and to consider adverse reports in its risk analysis.

189. This breach caused Plaintiff's damages because but for Defendants failure to comply with federal law and disclose, consider, and include in their risk management plans and/or labeling the thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, Plaintiff would not have been implanted with

Essure and therefore would also not have been injured by Essure. Instead, Defendants failed to have a complete Risk Management Plan in place thereby precluding Plaintiff and their implanting physicians from knowing of the thousands of migrations, perforations, pregnancies, device failures and malfunctions. This was actively concealed by Defendants.

190. This breach caused Plaintiff's damages noted above.

191. As a result of Defendants' negligence individually, jointly, and severally, Plaintiff sustained the injuries and exacerbations noted above.

192. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

193. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

194. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

195. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable

consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

BREACH OF EXPRESS WARRANTY- COUNT III

196. Plaintiff re-alleges and re-incorporates the preceding Paragraphs and pleads in the alternative to Counts IV.

197. The FDA's CPMA order confirms that: the FDA "does not evaluate information related to contractual liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

198. This claim arises out of injuries caused by Defendants' express warranties to Plaintiff which were specifically negotiated and expressly communicated to Plaintiff by Defendants or its agents in such a manner that Plaintiff understood and accepted them.

199. Defendant made, and Plaintiff relied on, the following actual affirmations of fact or promises which formed the bases of the bargain between Plaintiff and Defendants:[21]

(a) "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty which was located on Defendants' website www.essure.com.The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the

[21] The warranties and misrepresentations relating to pregnancy apply to only those plaintiffs that became pregnant.

first year of commercial experience. Defendants concealed this information from Plaintiff.

(b) "There were Zero pregnancies in the clinical trials."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(c) "Physicians must be signed-off to perform Essure procedures"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted reliable physicians who were approved to perform her surgery.

iii. However, this warranty was false as Defendants failed to abide by the FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendants concealed this information from Plaintiff.

(d) "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under

which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiff. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. Defendants concealed this information from Plaintiff. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[22] Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(e) "Essure is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiff. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who

[22] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater.[23]

(f) "Correct placement…is performed easily because of the design of the micro-insert"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiff.

(g) "Essure is a surgery-free permanent birth control."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

(h) "Zero pregnancies" in its clinical or pivotal trials.

[23] *Id.*

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiff encountered this representation was via a brochure given to her at her implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiff.

(i) In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an Essure advertisement. The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted reliable physicians who were approved to perform her surgery.

iii. However, this warranty was false as Defendants "signed off" on "Essure physicians who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendants concealed this information from Plaintiff.

(j) You'll never have to worry about unplanned pregnancy again.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiff.

(k) Defendants marketed with commercials stating during the procedure: "the tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

(l) "Worry free"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that she did not have to worry about working or causing her serious health problems.

iii. However, Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiff. Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiff. Defendants' facility was also issued a notice of violation as it "no

longer uses pre-sterile and post-sterile cages." Defendants actively concealed this from Plaintiff. Defendants also was issued a notice of violation when it "failed to obtain a valid license…prior to manufacturing medical devices." Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiff. Defendants were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility Defendants actively concealed this from Plaintiff. Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(m) "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiff. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in

Form 483 issued to Defendants by the FDA. Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(n) "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause her serious health problems.

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiff. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issue another Form 483 for "failing to adequately document the situation."

(o) Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff

encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants also state that it is only after "The Confirmation" pregnancy cannot occur. i.e. the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[24].

(p) "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure is not "surgery-free", rather surgery is not required. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(q) Essure is a …permanent birth control procedure-without … the risks of getting your tubes tied.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an

[24] *Essure insert expulsion after 3-month hysterosalpingogram,* US National Library of Medicine, Garcia, Al.

advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiff.

(r) "The inserts are made from…safe, trusted material."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause her serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendants refer to Essure and classify it as a "drug."

(s) Defendants' Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiff encountered this representation was via a brochure given to them at their implanting

physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems. Moreover, Plaintiff wanted a birth control that did not irritate her uterus like other forms of birth control.

iii. However, this warranty was false as the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiff. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(t) "there was no cutting, no pain, no scars…"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that did not cause pain cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiff have experienced pain as a result of Essure. Defendants concealed this information from Plaintiff. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain. Defendants altered the records of at least one trial participant to reflect less pain.

200. Defendants' "affirmations of fact or promise" and "descriptions" created a basis of the bargain for Plaintiff as noted above.

201. The warranties were specifically negotiated, directed, intended, and expressly communicated to Plaintiff in such a manner that Plaintiff understood and accepted them. Moreover, Plaintiff provided reasonable notification of the breach.

202. These warranties, in effect, over-promoted Essure and nullified otherwise adequate warnings.

203. As a result of Defendants' warranties and Plaintiff's reliance on same, Plaintiff has suffered damages. Specifically, the Essure device did not perform as warranted and instead migrated, perforated and/or broke resulting in the injuries noted above.

204. As a result of Defendants' breaches individually, jointly, and severally, Plaintiff sustained the injuries and exacerbations noted above.

205. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

206. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

207. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

208. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENT MISREPRESENTATION – COUNT IV

209. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

210. Defendants made the following misrepresentations:

(a) "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty which was located on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(b) "There were Zero pregnancies in the clinical trials."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(c) "Physicians must be signed-off to perform Essure procedures"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable physician who was approved to perform her surgery.

iii. However, this warranty was false as Defendants failed to abide by the FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendants concealed this information from Plaintiff.

(d) "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiff. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month

Confirmation Test was confirmed. Defendants concealed this information from Plaintiff. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.25 Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(e) "Essure is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiff. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[26].

(f) "Correct placement…is performed easily because of the design of the micro-insert"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under

[25] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.
[26] *Id.*

which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiff.

(g) "the Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted an implanting physician that was properly trained on placing the device and managing any technical issues.

iii. However, this warranty was false as Defendants failed to train the implanting physicians pursuant to the FDA guidelines. Defendants concealed this information from Plaintiff.

(h) "In order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the

awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted an implanting physician that was properly trained on placing the device and managing any technical issues.

iii. However, this warranty was false as Defendants "signed off" on the implanting physicians who were not a skilled operative hysteroscopist, in order to monopolize and capture the market, including the implanting physicians. Defendants concealed this information from Plaintiff.

(i) "Essure is a surgery-free permanent birth control."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

(j) "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiff encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiff.

(k) In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty located on an Essure advertisement. The circumstances under which Plaintiff encountered this representation was via a brochure given to her at her implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable Physician who was approved to perform her surgery.

iii. However, this warranty was false as Defendants "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendants concealed this information from Plaintiff.

(l) You'll never have to worry about unplanned pregnancy again.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiff.

(m) Defendants marketed with commercials stating during the procedure: "the tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

(n) "Worry free"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that she did not have to worry about working or causing her serious health problems.

iii. However, Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiff. Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiff. Defendants' facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages." Defendants actively concealed this from Plaintiff. Defendants also was issued a notice of violation when it "failed to obtain a valid license…prior to manufacturing medical devices." Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiff. Defendants were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. Defendants

actively concealed this from Plaintiff. Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(o) "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiff. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483 issued to Defendants by the FDA. Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(p) "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause her serious health problems.

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiff. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issue another Form 483 for "failing to adequately document the situation."

(q) Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants also state that it is only after "The Confirmation" pregnancy cannot occur. i.e. the complete opposite of what is warranted in the brochure. Adverse

Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[27].

(r) "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure is not "surgery-free", rather surgery is not required. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(s) Essure is a …permanent birth control procedure-without … the risks of getting your tubes tied.

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

[27] *Essure insert expulsion after 3-month hysterosalpingogram,* US National Library of Medicine, Garcia, Al.

iii. However, this warranty was false as Essure does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiff.

(t) "The inserts are made from…safe, trusted material."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause her serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendants refer to Essure and classify it as a "drug."

(u) Defendants' Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiff encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems. Moreover, Plaintiff wanted a birth control that did not irritate her uterus like other forms of birth control.

iii. However, this warranty was false as the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiff. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(v) "there was no cutting, no pain, no scars…"

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiff saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiff encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiff read and saw the warranty and wanted a reliable type of birth control that did not cause pain cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiff has experienced pain as a result of Essure. Defendants concealed this information from Plaintiff. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain. Defendants altered the records of at least one trial participant to reflect less pain.

211. Plaintiff justifiably relied on the misrepresentations. Specifically, Plaintiff would have never had Essure implanted had she been aware of the falsity of the representations specifically delineated in the preceding paragraphs which violate both Federal law and the CPMA.

212. Moreover, these misrepresentations, in effect, over-promoted Essure and nullified otherwise adequate warnings.

213. As a result of Defendants' misrepresentations and Plaintiff's reliance on same, Plaintiff has suffered damages. Specifically, the Essure device did not perform as represented and instead migrated, perforated and/or broke resulting in the injuries noted above.

214. As a result of Defendants' negligence individually, jointly, and severally, Plaintiff sustained the injuries and exacerbations noted above.

215. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

216. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

217. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

218. Plaintiff has suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable

consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENCE-FAILURE TO WARN– COUNT V

219. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

220. Plaintiff's injuries were caused by the negligent and reckless conduct of Defendants in failing to warn Plaintiff or their implanting physicians, all of which hinge on violations of Federal law and its CPMA.

221. Defendants had a duty to warn Plaintiff and/or their implanting physicians consistent with Federal law and its CMPA and included:

(a) 21 C.F.R. 814, governing premarket approval of medical devices, a Statement of material fact means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(b) 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device.

(c) 21 C.F.R. 820.65- establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

(d) 21 C.F.R. 803.1(a)- This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow-up. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(e) 21 C.F.R. 803.10- (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.(2) Submit annual reports (described in 803.33) to us.(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or(ii) Submit reports of device-related malfunctions to the manufacturer.(2) [Reserved](c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or(ii) A reportable event for which we made a written request.(3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(f) 21 C.F.R. 803.50(a)- (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:(1) May have caused or contributed to a death or serious injury; or(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.(b) What information does FDA consider "reasonably known" to me?(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;(ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(g) 21 C.F.R. 803.53- You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that:(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(h) 21 C.F.R. 806.10- (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:(1) To reduce a risk to health posed by the device; or(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b).(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.(c) The manufacturer or importer shall include the following information in the report:(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device

is a pre-amendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.(9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.(10) The date of manufacture or distribution and the device's expiration date or expected life.(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.(12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.(d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.(e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013]

(i) 21 C.F.R. 814.84-(a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.(b) Unless FDA specifies otherwise, any periodic report shall:(1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b).(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.(3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter.(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(j) 21 C.F.R. 820.65- Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(k) 21 C.F.R. 822-Post market surveillance- This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:(a) Failure of the device would be reasonably likely to have serious adverse health consequences;(b) The device is intended to be implanted in the human body for more than 1 year;… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(l) 21 C.F.R. 820.100(a) 6 -7- Corrective and Preventive Action-(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:(1) Analyzing processes, work operations, concessions, quality audit

reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.(b) All activities required under this section, and their results, shall be documented.

(m) 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;(2) Monitoring and control of process parameters and component and device characteristics during production;(3) Compliance with specified reference standards or codes;(4) The approval of processes and process equipment; and(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.(b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40.(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.(h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(n) 21 C.F.R. 820.90-(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.(b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

(o) 21 C.F.R. 820.90-(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

(p) 21 C.F.R. 820.180- All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(q) 21 C.F.R. 820.198-(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:(1) All complaints are processed in a uniform and timely manner;(2) Oral complaints are documented upon receipt; and(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device

Reporting.(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:(1) Whether the device failed to meet specifications;(2) Whether the device was being used for treatment or diagnosis; and(3) The relationship, if any, of the device to the reported incident or adverse event.(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:(1) The name of the device;(2) The date the complaint was received;(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;(4) The name, address, and phone number of the complainant;(5) The nature and details of the complaint;(6) The dates and results of the investigation;(7) Any corrective action taken; and(8) Any reply to the complainant.(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:(1) A location in the United States where the manufacturer's records are regularly kept; or(2) The location of the initial distributor.

(r) 21 C.F.R. 820.30 - Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(s) 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- A drug or device shall be deemed to be misbranded…If its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

(t) 21 U.S.C. 351(a) (h)- A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may

have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if is…not in conformity with …an applicable condition prescribed by an order.

(u) 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

(v) FDA requirement in CPMA order- "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(w) FDA requirement in CPMA order- "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(x) FDA requirement in CPMA order- Report Due Dates- six month, one year, eighteenth month, and two year reports.

(y) FDA requirement in CPMA order- A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

(z) FDA requirement in CPMA order- Warranties are truthful, accurate, and not misleading…Warranties are consistent with applicable Federal and State law.

222. Defendants breached these duties by not complying with its CPMA or Federal law:

(a) Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month and two year reports. All reports failed to meet the respective deadlines.

(b) Defendants failed to document successful placement of Essure concealing the failure rates.

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report 8 perforations which occurred as a result of Essure and was cited for the same by the FDA via Form 483.[28]

(d) Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendants failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in Form 483.

(e) Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints.

(f) Defendants excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendants had violated the FDCCA.

(g) erroneously using non-conforming material in the manufacturing of Essure;

(h) failing to use pre-sterile and post-sterile cages;

(i) manufacturing Essure at an unlicensed facility;

(j) manufacturing Essure for three years without a license to do so.

(k) Not reporting … complaints in which their product migrated;

(l) Not considering these complaints in their risk analysis for the design of Essure;

(m) Failing to document CAPA activities for a supplier corrective action;

[28] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

(n) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." Form 483/Violation form issued by Timothy Grome on January 6, 2011. These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

(o) Defendants had notice of 168 perforations but only disclosed 22 to the FDA. *Id.*

(p) On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

(q) On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented.

(r) On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)

(s) On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

(t) Defendants failed to disclose to Plaintiff and their implanting physicians the fact that it Defendants altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

223. Had Defendants disclosed such information as was required by its CPMA and Federal law to Plaintiff or Implanting Physicians, Plaintiff would have never had Essure implanted in them and would have avoided injuries.

224. At all times referenced herein, Defendants and each of them were acting as agents and employees of each of the other defendants and were acting within the scope, purpose and authority of that agency and employment and with full knowledge, permission and consent of each other Defendant.

225. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the injuries noted above.

226. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

227. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

228. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and may have to endure significant financial expenditures into the foreseeable future.

229. Plaintiff has suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, punitive

damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

LOSS OF CONSORTIUM – COUNT VI

230. Plaintiffs re-allege and re-incorporate the preceding Paragraphs.

231. At all relevant times hereto, Plaintiffs were lawfully married.

232. For the reasons set forth herein, Consortium Plaintiff Husband has necessarily paid and has become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

233. For the reasons set forth herein, Consortium Plaintiff Husband has suffered and will continue to suffer the loss of his spouse's support, companionship, services, society, love and affection.

234. Consortium Plaintiff Husband alleges that his marital relationship with Plaintiff Wife was impaired and deprecated, and the marital association between husband and wife has been altered.

235. Consortium Plaintiff Husband has suffered great emotional pain and mental anguish and will in the future suffer great emotional pain and mental anguish as a proximate result of Defendants' misconduct.

236. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe emotional distress, economic losses and other damages, for which they are entitled to compensatory damages.

237. Defendants are liable to Consortium Plaintiff Husband jointly and severally for all general and special relief, to which he is entitled by law.

WHEREFORE, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against all Defendants and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial with regards to all claims.

DATED this 1st day of October, 2018.

Respectfully submitted,

LECKMAN LAW, LLC

/s/ T. Matthew Leckman
T. Matthew Leckman
Attorney I.D. No. 92241
527 Bethan Road
Elkins Park, PA 19027
T: (215) 635-0584
matt@leckmanlaw.com

Attorney for Plaintiffs

VERIFICATION

I, T. Matthew Leckman, verify that upon my knowledge or information and belief the facts set forth in the foregoing Complaint are true and correct to the best of my knowledge. This statement is made subject to the penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.

DATED this 1st day of October, 2018.

/s/ T. Matthew Leckman
T. Matthew Leckman
Attorney for Plaintiffs

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2002

Ms. Cindy Domecus
Senior Vice President
Clinical Research and Regulatory Affairs
Conceptus, Inc.
1021 Howard Avenue
San Carlos, California 94070

Re: P020014
Essure™ System
Filed: April 22, 2002
Amended: May 3, 16, 28, June 7, 13, 24, July 18, 22, August 21, 23,
September 4, 16, 23, 27, 30, and October 16, 18, 21 and 22, 2002
Procode: 85 HHS

Dear Ms. Domecus:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) had completed its review of your premarket approval application (PMA) for the Essure™ System. This device is indicated for permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the post approval requirements outlined in the enclosure, you have agreed to provide the following data in post approval reports:

1. 5-Year Follow-up under Phase II and Pivotal Trials

In order to gather long-term safety and effectiveness data on the Essure™ System, you are required to follow participants who are not relying on Essure™ for contraception for safety evaluation only, at 2, 3, 4, and 5 years after *implantation.* You are required to follow

participants who are relying on Essure for contraception for both safety and effectiveness at 2, 3, 4, and 5 years after *discontinuation of alternative contraception.* Data collected should include the following:

a. pregnancies and outcomes;

b. adverse events; and,

c. histological explant data following any extirpative surgeries, if available.

Reports must be submitted annually. When a full five-year follow-up report is submitted, FDA will determine if continued follow-up of these study subjects is required. Please be advised that the results from this follow-up must be included in the labeling as these data become available. Potentially, this could mean that annual revisions to the labeling will be necessary. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

2. Post approval study in the U.S. with newly trained physicians.

This study is intended to document the bilateral placement rate for newly trained physicians (800 patients, 40 physicians, first 20 attempts). These data will be used to evaluate the training procedures and to update labeling. Data collected should include the following:

a. rates of successful bilateral placement of the Essure™ System at first attempt; and

b. identification of factors predictive of failure to achieve bilateral placement of the Essure™ System at first attempt.

Expiration dating for this device has been established and approved at nine months. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an

independent advisory committee, under section 515(g) of the Federal Food, Drug and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Lisa Lawrence at (301)594-1180.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Conditions of Approval

Last Modified: 1-31-02

CONDITIONS OF APPROVAL

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations that require a PMA supplement cannot be briefly summarized; therefore, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device 30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

1. Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

2. Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

   a. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

   b. reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

1. A mix-up of the device or its labeling with another article.

2. Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and:

   a. has not been addressed by the device's labeling; or

   b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency.

3. Any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.
The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.

EXHIBIT C

Premarket Approval (PMA)

1 to 46 of 46 Results

Records per Page 500

PMA Number: *P020014* **Decision Date to** *03/15/2018*

New Search[6]

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Device	Applicant	PMA Number	Decision Date
Essure System For Permanent Birth Control[16]	BAYER PHARMA AG	P020014 S049	12/04/2017
Essure System For Permanent Birth Control[17]	BAYER PHARMA AG	P020014 S048	12/14/2016
Essure System[18]	BAYER PHARMA AG	P020014 S046	11/15/2016
Essure System For Permanent Birth Control (Model Ess305)[19]	BAYER PHARMA AG	P020014 S047	09/29/2016
Essure System[20]	BAYER PHARMA AG	P020014 S044	05/12/2016
Essure System[21]	BAYER PHARMA AG	P020014 S045	04/28/2016
Essure System For Permanent Birth Control[22]	BAYER PHARMA AG	P020014 S041	06/29/2015
Essure System[23]	BAYER PHARMA AG	P020014 S043	06/09/2015
Essure System For Permanent Birth Control[24]	BAYER PHARMA AG	P020014 S042	12/11/2014
Essure[25]	BAYER PHARMA AG	P020014 S040	10/30/2013
Essure System[26]	BAYER PHARMA AG	P020014 S039	12/20/2012
Conceptus Essure System[27]	BAYER PHARMA AG	P020014 S038	10/02/2012
Conceptus Essure System[28]	BAYER PHARMA AG	P020014 S037	05/17/2012
Conceptus Essure System For Permanent Birth Control[29]	BAYER PHARMA AG	P020014 S036	04/19/2012
Conceptus Essure System For Permanent Birth Control[30]	BAYER PHARMA AG	P020014 S035	03/19/2012
Conceptus Essure System For Permanent Birth Control[31]	BAYER PHARMA AG	P020014 S017	02/24/2012
Conceptus Essure System[32]	BAYER PHARMA AG	P020014 S033	02/22/2012
Conceptus Essure System For Permanent Birth Control[33]	BAYER PHARMA AG	P020014 S034	07/01/2011
Conceptus Essure System For Permanent Birth Control[34]	BAYER PHARMA AG	P020014 S032	02/24/2011
Conceptus Essure System For Permanent Birth Control[35]	BAYER PHARMA AG	P020014 S029	04/06/2010
Conceptus Essure System For Permanent Birth Control[36]	BAYER PHARMA AG	P020014 S030	02/15/2010
Conceptus Essure System[37]	BAYER PHARMA AG	P020014 S024	08/26/2009
Essure System[38]	BAYER PHARMA AG	P020014 S026	07/16/2009
Conceptus Essure System For Permanent Birth Control[39]	BAYER PHARMA AG	P020014 S027	06/19/2009
Conceptus Essure System For Permanent Birth Control[40]	BAYER PHARMA AG	P020014 S025	06/11/2009
Conceptus Essure System For Permanent Birth Control[41]	BAYER PHARMA AG	P020014 S022	04/20/2009
Conceptus Essure System For Permanent Birth Control[42]	BAYER PHARMA AG	P020014 S018	03/16/2009
Conceptus Essure System For Permanent Birth Control[43]	BAYER PHARMA AG	P020014 S023	03/09/2009
Essure System[44]	BAYER PHARMA AG	P020014 S021	11/07/2008
Essure Contraceptive Tubal Occlusion Device And Delivery Sys[45]...	BAYER PHARMA AG	P020014 S019	10/08/2008
Conceptus Essure System[46]	BAYER PHARMA AG	P020014 S020	09/11/2008
Essure System[47]	BAYER PHARMA AG	P020014 S015	06/10/2008
Conceptus Essure System For Permanent Birth Control[48]	BAYER PHARMA AG	P020014 S014	08/07/2007
Conceptus Essure System For Permanent Birth Control[49]	BAYER PHARMA AG	P020014 S012	06/15/2007
Conceptus Essure System For Permanent Birth Control[50]	BAYER PHARMA AG	P020014 S010	10/11/2006
Essure Permanent Birth Control System[51]	BAYER PHARMA AG	P020014 S013	09/19/2006
Essure System[52]	BAYER PHARMA AG	P020014 S009	07/12/2005
Essure System[53]	BAYER PHARMA AG	P020014 S008	01/31/2005
Essure System[54]	BAYER PHARMA AG	P020014 S006	07/22/2004
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Essure System[61]	BAYER PHARMA AG	P020014	11/04/2002

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Page Last Updated: 03/12/2018

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52. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S009
53. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S008
54. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S006
55. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S005
56. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S007
57. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S004
58. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S002
59. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S003
60. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S001
61. /scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014

EXHIBIT D

FDA Activities: Essure

The FDA continues to monitor the safety of Essure. The FDA continues to believe that the benefits of the device outweigh its risks, and that Essure's updated labeling helps to assure that women are appropriately informed of the risks. The following is an overview of some of the FDA's efforts to monitor the safety of Essure.

Reviewing Ongoing Clinical Study to Gather More Information on Essure Benefits and Risks

The FDA ordered Bayer, the company that makes Essure, to conduct a postmarket surveillance study to gather more data about Essure's benefits and risks. The FDA approved the study plan on September 2, 2016, and will make interim study results and updates available on the **Essure Postmarket Surveillance Study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=356&c_id=3854)** page. The FDA believes clinical data will help to better understand certain patient complications that may be experienced by women who have Essure permanent birth control when compared to women who undergo tubal ligation.

Results collected from the approved study plan will also help the agency better understand the underlying reasons that may prevent completion of the third step of the Essure System method (confirmation of proper location/occlusion). Findings from the study may serve to inform future FDA actions.

Issued Final Guidance to Improve Labeling for Essure and Similar Devices

On October 31, 2016, the FDA issued the **final guidance (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf)**, "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization" after carefully considering public comments. To view the comments received, go to the **Public Docket (http://www.regulations.gov/)** and search Docket # FDA-2016-D-0435. Updated **Essure Labeling Information for Patients and Health Care Providers (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm)** is available online.

In issuing this guidance, the FDA considered feedback from the 2015 Advisory Committee meeting, as well as comments FDA received through open public dockets. Panel members and the public indicated that medical device labeling for permanent birth control methods, including Essure, is not clear and many patients do not receive enough information before making a decision. Panel members recommended changes to the patient and physician labeling and more aggressive methods to ensure patients are well-informed of risks before choosing a permanent birth control method.

To help address these concerns, the FDA identifies content and format for certain information to be included in the patient and physician labeling to guide conversations between women and their health care providers about the benefits and risks of this type of device:

- A boxed warning with safety statements to better communicate to patients and providers the significant side effects or complications associated with these devices and information about the potential need for removal;
- A Decision Checklist with key items about the device, its use, and safety and effectiveness outcomes, which the patient should be aware of as they consider permanent birth control options.

Completed Evaluation of the Trade Complaint Regarding Allegations Initially Made in a Citizen Petition (https://www.regulations.gov/document?D=FDA-2015-P-0569-0001)

The Citizen Petition, which included allegations related to Essure, was referred to the Office of Compliance within the Center for Devices and Radiological Health (CDRH). CDRH closed the Citizen Petition, and the Office of Compliance has completed its investigation of the **trade complaint (http://www.regulations.gov/#!documentDetail;D=FDA-2015-P-0569-0005)**.

Allegations in the trade complaint included clinical trial misconduct, notably that clinical trial participants' medical records were altered to reflect more favorable data about participants' experiences. Additionally, the complaint alleged that the sponsor violated the terms of the PMA approval order and violated laws that relate to the manufacturing and marketing of Essure.

The FDA inspected Bayer as part of the complaint investigation. In addition, Bayer provided the FDA with the available case report forms that documented patient experiences during Essure clinical trials.

The FDA analyzed these forms to evaluate the incidence of cross-outs and discrepancies regarding patient-reported pain, comfort and satisfaction ratings to assess whether modifications favored Essure safety and effectiveness. The Agency found that less than 1 percent of case report form data pertaining to pain, bleeding, device placement/movement and pregnancy were changed during the clinical trials. Although modifications to the case report forms were identified, our analysis did not find evidence the sponsor purposefully modified patient responses to reflect more favorable data for Essure. More information about the Agency's case report form analysis can be found in the **Summary and Key Findings document (/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/UCM488062.pdf)**.

Also as part of the Agency's complaint investigation, CDRH evaluated Bayer's labeling of the device, taking into account the allegations in the complaint, as well as the feedback received during the September 2015 Advisory Committee meeting and from public comments received in response to the public docket. With the issuance of the final guidance and the subsequent approval of Bayer's labeling changes that are consistent with the recommendations in the guidance, the Agency considers its investigation of the trade complaint completed. CDRH Office of Compliance will ensure that Bayer's revisions to their marketing and promotional materials are consistent with the updated labeling.

Continued Reviews of Reported Problems

The FDA relies on a variety of postmarket surveillance data sources to monitor the safety and effectiveness of medical devices. The FDA continues to review the available information about Essure and the experiences of patients who have had Essure since the FDA approved it in 2002. This includes experiences of patients who have had positive outcomes with Essure as well as those who have experienced problems. Postmarket surveillance activities for Essure include:

Analyzing Essure patient reports of problems (including Web-based testimonials) and reports of problems submitted to the FDA from other sources, including doctors, patients, and the manufacturer of Essure

Adverse event and product problem reports submitted to the FDA are one source the FDA uses to monitor marketed medical devices. These reports may contribute to the detection of potential device-related safety issues as well as to the benefit-risk assessments of these devices. While such reports are a valuable source of information, this type of reporting system has notable limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. This can make it difficult for the agency to confirm whether a device caused a specific event based only on the information provided in a medical device report. Complaints or adverse

event reports do not necessarily directly indicate a faulty or defective medical device, and adverse event reports alone cannot be used to establish or compare rates of event occurrence. Additionally, we may receive multiple reports related to the same event, making it difficult to determine actual numbers of events.

The FDA conducted a search of the Manufacturer and User Facility Device Experience (MAUDE) database on January 5, 2018. From November 4, 2002, Essure's approval date, through December 31, 2017, the FDA received 26,773 medical device reports related to Essure. A majority of reports received between 2013 and 2015 were voluntary reports submitted from women who received Essure implants. Beginning in 2016, most of the reports received were submitted by the manufacturer. In 2017, 94.6 percent of reports received were submitted by the manufacturer.

The total number of medical device reports received related to Essure in 2017 is 11,854, an increase from the total number received in 2016 (5,019). The nature and severity of the reports remain consistent with prior years; however, in 2017, 78 percent of all manufacturer-submitted reports cited litigation, and may be referencing reports previously submitted to the FDA.

Also, in 2017, 92.7 percent of all reports recieved used terms related to device removal, but some of these reports may not indicate that the device was removed or the date of removal. The FDA is currently evaluating individual reports to better understand reasons for the device removal and patient outcomes where that information is provided. The FDA will keep the public informed if significant new information becomes available.

From 2002 through 2017, the most frequently-reported patient problems were pain/abdominal pain (21,215), heavier menses/menstrual irregularities (9,846), headache (7,231), fatigue (5,842), and weight fluctuations (4,970). Most of the reports received listed multiple patient problems in each report. The most frequent device problems reported were patient-device incompatibility example, possible nickel allergy (4,481), migration of the device or device component (2,936), dislodged or dislocated device (1,356), device breakage (1,044), device operating differently than expected (947), device difficult to remove (331), device difficult to insert (317), and malposition of the device (279). Multiple device problems can also be listed in each report.

Through December 31, 2017, there have been 48 reports coded by the submitter as death. Eight of these were incorrectly coded, as there was no indication of death in the report. Of the remaining 40, ten reports relate to eight adult deaths; 23 reports relate to 20 incidences of pregnancy loss; four reports relate to four incidents of a death of an infant after live birth; two reports relate to two incidences of ectopic pregnancies (a complication of pregnancy in which the fertilized egg attaches outside the uterus); and one report specifies a death but does not indicate whether the death was before or after birth. It is difficult for the FDA to determine whether the device caused the death with only the information provided in the report.

The FDA has received a total of 1,826 reports of pregnancies in patients with Essure from 2002 through 2017. Some reports contained information on multiple pregnancies or more than one pregnancy loss. Of the total reports: 365 live births were reported; 623 did not indicate whether the pregnancy resulted in a live birth or pregnancy loss; and 875 pregnancy losses were reported.

Among the 875 pregnancy losses reported: 327 were reported as ectopic pregnancies; 112 were reported as elective terminations of pregnancies, and 451 were reported as other pregnancy losses.

Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report.

Reviewing results from Post-Approval Studies (PAS)

Essure's 2002 approval required two PAS. **PAS I (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm?t_id=90320&c_id=260#tt)** was conducted to gather five-year follow up information on the participants in two groups of patients that were part of premarket clinical trials (known as Phase 2 trial and Pivotal Trial). The study evaluated:

- how well Essure prevented pregnancy;
- the safety of the procedure used to place Essure; and,
- the safety of Essure once implanted, including patient comfort.

Although there is evidence of complications, as there are with many medical devices, overall results from this study did not demonstrate any new safety problems or an increased incidence of problems since the time of device approval.

PAS II (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm?t_id=90320&c_id=23#tt) was conducted to evaluate bilateral placement rate (insert placement in both the right and the left Fallopian tubes at first attempt) for newly trained physicians in the U.S. Data from this study were used to evaluate the training procedures and to update labeling.

You can view a **summary of Essure PAS results (/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/UCM452291.pdf)** for the two studies ordered in conjunction with the PMA approval, which have been extracted from the **Post-Approval Study Status web page (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm)**.

Subsequent to the product's approval in 2002, three PMA supplements were approved with post-approval studies required as conditions of approval. One supplement was related to device modifications; the other two supplements supported labeling modifications. Details on the study protocols and status are posted on the **Post-Approval Study Status web page (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm)**.

Evaluating the available clinical literature to better understand long-term complications

FDA sought to determine what long-term complications may be associated with Essure more than five years after placement, because the post-approval study evaluated safety and effectiveness only up to five years. The **Executive Summary ()** prepared for the Advisory Committee meeting provides a comprehensive overview of clinical literature, in which we found no conclusive evidence indicating any new or more widespread complications definitely associated with Essure occurring more than five years after Essure placement.

Convened FDA Advisory Committee to discuss Essure Safety and Effectiveness

As part of examining safety concerns about Essure raised by patients and cited in Medical Device Reports (MDRs), the FDA convened a meeting of the **Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015 (https://wayback.archive-it.org/7993/20170112001932/http:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm4634)** to:

- discuss currently available scientific data pertaining to Essure's safety and effectiveness,
- hear expert scientific and clinical opinions on the risks and benefits of the device, and
- hear concerns and experiences of women implanted with Essure.

The **Advisory Committee meeting summary ()** provides a comprehensive overview of Essure and the FDA's review, including post-market information, clinical literature and information from ongoing studies.

Additional Information

- **CDRH FOIA: How to Get Records from CDRH (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/default.htm)**
- **Essure Postmarket Surveillance Study Page (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=356&c_id=3854)**

More in Essure Permanent Birth Control (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm)

Essure Benefits and Risks (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452250.htm)

Essure Permanent Birth Control: Information for Patients (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452251.htm)

Essure Permanent Birth Control: Information for Health Care Providers (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452252.htm)

FDA Activities: Essure (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm)

Essure Permanent Birth Control: Reporting Problems to the FDA (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452269.htm)

Regulatory History (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm)

Essure Labeling Information for Patients and Health Care Providers (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452280.htm)